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Registration Decision RD2015-07

Extract of *Reynoutria sachalinensis*

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Registration Decision for Extract of *Reynoutria sachalinensis*

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of *Reynoutria sachalinensis* Bioprotectant Technical and Regalia Maxx Biofungicide Liquid Concentrate, containing the technical grade active ingredient extract of *R. sachalinensis*, for partial suppression of dollar spot and foliar anthracnose in turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2014-22, *Extract of* Reynoutria sachalinensis. This Registration Decision[2] describes this stage of the PMRA's regulatory process for extract of *R. sachalinensis* and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2014-22. This decision is consistent with the proposed registration decision stated in PRD2014-22.

For more details on the information presented in this Registration Decision, please refer to PRD2014-22, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website.

What Is Extract of *Reynoutria sachalinensis*?

The active ingredient is a plant extract from giant knotweed (*R. sachalinensis*). When sprayed on certain plant species, the extract triggers an induced systemic resistance response that acts as an internal defence mechanism against plant pathogens. In turn, this response can suppress the development of disease in treated plants.

Health Considerations

Can Approved Use of Extract of *Reynoutria sachalinensis* on Turf Affect Human Health?

Extract of *R. sachalinensis* is unlikely to affect human health when used according to label directions.

Potential exposure to extract of *R. sachalinensis* may occur when handling and applying the product or when people enter a freshly treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, extract of *R. sachalinensis*, is anticipated to be of low acute toxicity by the oral, dermal and inhalation routes and minimally irritating to eyes and skin, and is not a skin sensitizer. There is no information available in the published scientific literature that suggests extract of *R. sachalinensis* is carcinogenic, genotoxic, neurotoxic or is a developmental/reproductive toxicant. Moreover, the plant has long been used as a food ingredient and in medicinal products, in some parts of the world, with a history of safe consumption.

The end-use product is of low acute toxicity by oral, dermal and inhalation routes, is moderately irritating to eyes, mildly irritating to skin, and is not a dermal sensitizer. Due to the irritation potential of the end-use product and the likely exposure of workers and commercial applicators to it via inhalation and contact with skin and eyes, personal protective equipment, precautionary statements, and a restricted-entry statement are required on the label to mitigate any exposure concerns.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern.

Regalia Maxx Bioprotectant Liquid Concentrate is proposed for use on turf. Consequently, adults, youths and toddlers may be exposed to extract of *R. sachalinensis* through contact on treated turf. However, risk to the general population is not a concern since the end-use product is of low toxicity and entry to freshly treated sites is not permitted until sprays have dried.

Occupational Risks From Handling Regalia Maxx Biofungicide Liquid Concentrate for Use in Turf

Occupational risks are not of concern when extract of *R. sachalinensis* is used according to label directions, which include protective measures.

Occupational exposure to individuals mixing, loading, or applying Regalia Maxx Bioprotectant Liquid Concentrate is not expected to result in unacceptable risk when the product is used according to label directions. For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible.

Precautionary measures (for example, wearing of personal protective equipment) and hygiene statements on the end-use product label aimed at mitigating exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Extract of *Reynoutria sachalinensis* Is Introduced into the Environment?

***Reynoutria Sachalinensis* is not persistent and the proposed use is not expected to pose a risk to non-target terrestrial or aquatic organisms.**

The active ingredient, extract of *R. sachalinensis* is a naturally occurring constituent of the plant, *R. sachalinensis* (common name: giant knotweed). As such, it is expected to break down completely within a relatively short period of time and therefore will not be persistent in the environment. Use of Regalia Maxx Biofungicide Liquid Concentrate (containing extract of *R. sachalinensis*) on turf is not expected to cause adverse effects to non-target terrestrial and aquatic organisms.

Value Considerations

What Is the Value of Regalia Maxx Biofungicide Liquid Concentrate for Use in Turf?

Regalia Maxx Biofungicide Liquid Concentrate triggers natural defence mechanisms in treated plants that can suppress the development of certain plant diseases caused by fungal and bacterial pathogens. Preventative application of this product will reduce plant and turf disease development. It is most appropriate for use under low disease pressure. Resistance to the active ingredient is unlikely to develop because of the complex nature of its mode of action. This product can be a valuable component of an integrated disease management program.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Regalia Maxx Biofungicide Liquid Concentrate to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The label has the restricted-entry statement, "Do not re-enter or allow entry into treated areas until the spray is dried."

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-22) are available for public inspection, upon application, in the PMRA Reading Room (located in Ottawa). For more information, please contact the PMRA Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA Pest Management Information Service.

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[5] As per subsection 35(1) of the *Pest Control Products Act*.